

I. REMARKS

A. Amendments

Applicants note that the Office Action Summary reflects that Claims 1-37 are pending in the instant application. However, on September 14, 2004, Applicants filed a Preliminary Amendment adding new Claims 38-46. A copy of the Preliminary Amendment is attached in Appendix A.

B. Election of Coating Process

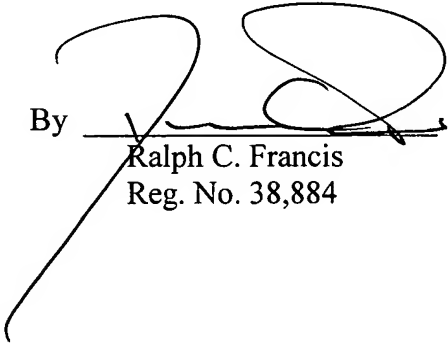
The Examiner has also requested that Applicants elect between the coating processes of "dipping" and "spraying". As indicated above, Applicants have deleted the claims directed to specific coating processes, including dipping and spraying. Applicants accordingly request that the election request relating to the coating processes be withdrawn.

If the Examiner has any further questions or wishes to address any other matter, Applicants invite the Examiner to call Applicants' attorney at the number given below to advance the prosecution of this matter

Respectfully submitted,

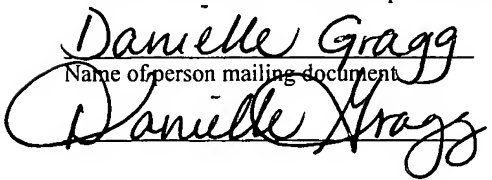
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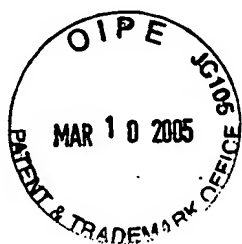
By


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Dated: March 7, 2005
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APPENDIX A

MESSAGE CONFIRMATION



SEP-14-2004 04:26 PM TUE

FAX NUMBER : 650 564 2195
 NAME : INTEL PROPERTY FAX

NAME/NUMBER : 817038729306
 PAGE : 19
 START TIME : SEP-14-2004 04:21PM TUE
 ELAPSED TIME : 04'22"
 MODE : STD ECM
 RESULTS : [O.K]

PTO/SB/21 (04-04)
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TRANSMITTAL FORM <small>(to be used for all correspondence after initial filing)</small>	Application Number	10/045,842
	Filing Date	October 26, 2001
	First Named Inventor	Michel J.N. Cornier
	Art Unit	3763
	Examiner Name	Unassigned
	Attorney Docket Number	ARC 3036 R1
Total Number of Pages in This Submission		19

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance Communication to Technology Center (TC)
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declarations(s)	<input type="checkbox"/> Power of Attorney, Revocation	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Change of Correspondence Address	<input checked="" type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Terminal Disclaimer	Preliminary Amendment, Amendment, Request and
<input type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> Request for Refund	Fee to Add Inventor, Declaration and Power of
<input type="checkbox"/> Certified Copy of Priority Document(s)	<input type="checkbox"/> CD, Number of CD(s)	Attorney, Declarations of Inventors, and Consent to
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	Remarks	Add Inventor
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53		

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Ralph Francis Francis Law Group	Registration No.
Signature	<i>[Signature]</i>	
Date	8.18.01	

CERTIFICATE OF TRANSMISSION/MAILING

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Typed or printed name		(703) 872-9306
Signature	Susan Ahearn	Date 9/14/04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF:

CORMIER, et al.

FOR: TRANSDERMAL DRUG DELIVERY
DEVICES HAVING COATED
MICROPROTRUSIONS

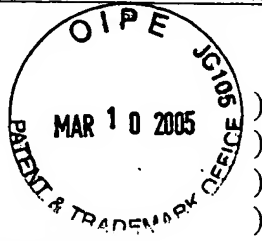
SERIAL NO: 10/045,842

FILED: October 26, 2001

ART UNIT NO: 3763

EXAMINER: To be Assigned

DOCKET NO: ARC 3036 R1



PRELIMINARY AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The following amendments and remarks are provided before the initial examination of the above-identified patent application. Examination and consideration of the above application in light of the following amendments and remarks is respectfully requested.

Please amend the application as follows:

Amendments to the Specification begin on page 2 of this paper.

Amendments to the Claims are reflected in the listing of claims, which begins on page 4 of this paper.

Remarks/Arguments begin on page 6 of this paper.

I. AMENDMENTS

Amendments to the Specification:

Please add the following new paragraph and heading before paragraph [0001]:

--CROSS REFERENCE TO RELATED APPLICATIONS

[0001] This application claims the benefit of U.S. Provisional Application No. 60/244,038, filed October 26, 2000.--

Please replace paragraph [0001] with the following amended paragraph:

~~{0001}~~ [0001.1] This invention relates to administering and enhancing transdermal delivery of an agent across the skin. More particularly, the invention relates to a percutaneous drug delivery system for administering a potent pharmacologically active agent through the stratum corneum using skin piercing microprotrusions which have a dry coating of the pharmacologically active agent. Delivery of the agent is facilitated when the microprotrusions pierce the skin of a patient and the patient's interstitial fluid contacts and dissolves the active agent.

Please replace paragraph [0028] with the following amended paragraph:

[0028] FIG. 8 is a graph showing the amount of ~~human growth hormone~~ desmopressin delivered by a microprotrusion array that has been tip-coated as described in Example 2B.

Please replace paragraph [0030] with the following amended paragraph:

[0030] FIG.10 is a graph showing the ~~amount~~ delivery efficiency of ovalbumin ~~delivered~~ administered by a microprotrusion array that has been tip-coated as described in Example 6B.

Please replace paragraph [0066] with the following amended paragraph:

[0066] Studies were performed in hairless guinea pigs to evaluate the kinetics of drug absorption through the skin from hGH tip-coated microprotrusion array systems. System application was performed on the flank of the anesthetized animals with an impact applicator delivering an energy of 0.26 J in less than 10 milliseconds. The system applied comprised a coated microprotrusion array device, adhered to the center of a LDPE backing with an adhesive (7 cm² disc). Systems remained on the skin for 5 seconds (n=3) or 5 minutes (n=5). A group of animals (n=5) received a subcutaneous injection of 10 µg hGH. Blood samples were collected at time intervals for plasma hGH determination by ELISA. The hGH dose delivered was extrapolated based on an area under the curve (AUC) calculation compared to IV administration of hGH. Results showed that hGH delivery from the microprotrusion array was the same with 5 seconds (open triangles) and 5 minutes (close circle) wearing times (FIG. 9). On average, 5 [[82 g]] µg of hGH was delivered in each animal, which accounts for approximately 50% of the coated dose. This is to compare with a bioavailability of 65% following subcutaneous administration of hGH, the results of which are shown as "X" (FIG.9).

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

Claim 38. (New) A method of transdermally delivering a pharmacologically active agent to a patient, comprising the steps of:

providing a microprotrusion member having a plurality of stratum corneum-piercing microprotrusions, said microprotrusion member having a coating disposed thereon, said coating including at least one pharmacologically active agent, said pharmacologically active agent being sufficiently potent to be therapeutically effective when administered in an amount less than about 1 mg; and

applying said microprotrusion member to a skin site on the patient, whereby said plurality of stratum corneum-piercing microprotrusions pierce the stratum corneum and deliver said pharmacologically active agent to the patient,

wherein said delivered pharmacologically active agent has improved pharmacokinetics compared to pharmacokinetics after subcutaneous injection.

Claim 39. (New) The method of Claim 46, wherein said pharmacologically active agent is selected from the group consisting of ACTH(1-24), calcitonin, desmopressin, LHRH, LHRH analogs, goserelin, leuprolide, PTH, vasopressin, deamino[Val4, D-Arg8] arginine vasopressin, buserelin, triptorelin, interferon alpha, interferon beta, interferon gamma, FSH, EPO, GM-CSF, G-CSF, IL-10, glucagon, growth hormone releasing factor (GRF), and analogs and pharmaceutically acceptable salts thereof.

Claim 40. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises increased bioavailability of said pharmacologically active agent.

Claim 41. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises an increase in C_{max} .

Claim 42. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises a decrease in T_{max} .

Claim 43. (New) The method of Claim 38, wherein said improved pharmacokinetics comprises an enhanced absorption rate of said pharmacologically active agent.

Claim 44. (New) The method of Claim 38, wherein said coating is formed from an aqueous solution having solubility greater than approximately 50 mg/ml.

Claim 45. (New) The method of Claim 44, wherein said aqueous solution has a viscosity less than approximately 500 centipoises.

Claim 46. (New) The method of Claim 38, wherein each of said plurality of stratum corneum-piercing microprotrusions has a length less than approximately 500 microns.

REMARKS

The foregoing amendments are made in order to place the Application in better condition for examination and to better define the invention. As no new matter is presented with these amendments, it is believed that such amendments may be entered and such action is respectively requested.

Respectfully submitted,
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By 

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